IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

THERASENSE, INC. et al.,

Plaintiffs,

v.

BECTON, DICKINSON AND COMPANY,

Defendant.
_____/

No. C04-02123 MJJ
No. C04-03327 MJJ
No. C04-03732 MJJ
No. C05-03117 MJJ

CLAIMS CONSTRUCTION ORDER

INTRODUCTION

Before the Court is Therasense Inc. ("Therasense"), Abbott Laboratories ("Abbot") (collective "Plaintiffs"), and Becton Dickinson and Co's. ("Defendant", "Becton") proposed construction of disputed terms in two patents held by Abbot. On March 15, 2006, the parties filed a joint claims construction statement with each party's proposed construction of terms.[1] On July 19, 2006, the Court held a hearing at which time the parties presented oral arguments in support of their respective constructions. The Court has read the moving and responding papers, including the patent-in-suit, considered the arguments of counsel, and now construes the disputed terms in the claims.

BACKGROUND

This case concerns the infringement of U.S. Patent number 5,628,890 (the " '890 patent") entitled "Electrochemical Sensor" and U.S. Patent number 6,143,164 (the " '164 Patent") entitled

[1]Second Revised Joint Claims Construction Statement, Filed March 30, 2006 (04-2123, Doc. No. 187).

"Small Volume in vitro Analyte Sensor." Both of the patents at issue are concerned with the management of the medical disorder known as diabetes. Type II diabetes is characterized by the inability to produce the needed amount of the hormone insulin, which in turn regulates the amount of glucose present in the blood. Diabetes patients typically manage their condition by measuring their blood glucose levels on a regular basis. Based upon these blood glucose measurements, they can take preventative measures, such as injecting insulin or ingesting carbohydrates, to adjust the glucose content in their blood to the appropriate level.

The '890 patent contains a design for a test strip which can be used by diabetes patients to measure their blood glucose levels. To use such a strip, individuals will typically puncture their finger to draw a small amount of blood onto the test strip. The strip is then inserted in an electronic blood glucose sensing device, which can determine the concentration of the glucose based upon the blood sample in the strip. The '164 patent claims a process for determining the concentration of substances or "analytes" in bodily fluids, once a given sample size of the fluid is obtained. Relevant to the instant case, the process described in the '164 patent can be used to measure the amount of glucose in a given blood sample.

The issue before the Court is the construction of two disputed terms from the '890 patent and three disputed terms for the '164 patent.

LEGAL STANDARD

The construction of a patent is a matter of law for the Court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). In construing terms, the Court must conduct an independent analysis of the claim terms; it is insufficient to simply choose between the competing constructions that the parties have submitted. *Exxon Chem. Patents v. Lubrizol Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995). To determine the meaning of a patent claim, the Court considers three sources: (1) the claims; (2) the specification; and (3) the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*), *aff'd*, *Markman*, 517 U.S. 370.

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed.

Cir. 2005) (*en banc*) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004). Accordingly, in construing disputed terms, the Court first looks to the words of the claims. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Generally, the Court ascribes the words of a claim their ordinary and customary meaning. *Id.* "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1313.

Other claims of the patent in question can also assist in determining the meaning of a claim term. *Vitronics*, 90 F.3d at 1582. Because an inventor normally uses claim terms consistently throughout a patent, the usage of a term in one claim may reveal the meaning of the same term in other claims. *See Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001). Conversely, use of a term in a different way in another claim may also be useful in determining the particular meaning of the disputed term. *See Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991). Particularly, the existence of a dependent claim that adds a particular limitation creates a presumption that the limitation in question is not present in the independent claim. *See Liebel-Flarseim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004); *Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1023 (Fed. Cir. 1987).

Because the claims are part of a fully integrated written instrument comprised principally of the specification, the Court must next review the specification. *Markman*, 52 F.3d at 978-79. Because the specification must contain a description of the invention that is clear and complete enough to enable those of ordinary skill in the art to make and use it, the specification is "always highly relevant" to the Court's claim construction analysis. *Vitronics*, 90 F.3d at 1582. "Usually, [the specification] is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* "In light of the statutory directive that the inventor provide a 'full' and 'exact' description of the claim invention, the specification necessarily informs the proper construction of the claims." *Phillips*, 415 F.3d at 1316. In some cases, the specification may reveal that the patentee has given a special definition to a claim term that differs from its ordinary meaning. "In such cases, the inventor's lexicography controls." *Phillips*, 415 at 1316. The specification also may reveal the

patentee's intentional disclaimer or disavowal of claim scope. "In that instance, as well, the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is regarded as dispositive." *Id.* "Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification of file history." Thus, the specification can act as a dictionary when it expressly or impliedly defines terms used in the claims. *Id.*

Next, in addition to reviewing the specification, the Court should consider the patent's prosecution history, if it is in evidence. *Markman*, 52 F.3d at 980. The prosecution is intrinsic evidence and consists of the complete record of the proceedings before the Patent and Trademark Office ("PTO") and includes the prior art cited during the examination of the patent. *Phillips*, 415 F.3d at 1317. "The prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower then it would otherwise be." *Phillips*, 415 F.3d 1317; *see also Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) ("The purpose of consulting the prosecution history in construing a claim is to exclude any interpretation that was disclaimed during prosecution.") (internal quotations omitted).

In addition to the foregoing intrinsic evidence, the Federal Circuit has also authorized district courts to rely on extrinsic evidence in claim construction, which consists of "all evidence external to the patent and prosecution history, including exert and inventor testimony, dictionaries, and learned treatises.' *Markman*, 52 F.3d at 980. However, extrinsic evidence is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004). "Because dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various field of science and technology, those resources have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention." *Phillips*, 415 F.3d 1318. Accordingly, the Court may consider this evidence, if the Court deems it helpful in deciphering the true meaning of the claim terms. *Id.*

Additionally, the Federal Circuit has recognized that, "extrinsic evidence in the form of expert testimony can be useful to a court for a variety of purposes, such as to provide background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Phillips*, 415 F.3d at 1318. At the same time, the Court must disregard an expert's conclusory, unsupported assertions regarding the definition of a claim term. *Id.* Likewise, the Court should discount expert testimony that is directly at-odds with the claim construction mandated by the intrinsic evidence. *Id.*; *see also Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998).

While extrinsic evidence may be useful to the court, it is unlikely to lead to a reliable interpretation of claim language unless considered in the context of the intrinsic evidence. *Id.* "Nevertheless, because extrinsic can help educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand claim terms to mean, it is permissible for the district court in its sound discretion to admit and use such evidence. In exercising that discretion, and in weighing all the evidence bearing on claim construction, the court should keep in mind the flaws inherent in each type of evidence and assess that evidence accordingly." *Id.* at 1319.

With these canons of construction in mind, the Court turns to the disputed claim terms.

DISPUTED CLAIM TERMS

The following is a list of disputed claim terms identified by the parties in their joint claims construction statement.

1) "sample transfer path"

('890 Patent, Claim 11)

2) "directional flow"

('890 Patent, Claim 11)

3) "unassisted flow"

('164 Patent, Claim 16)

4) "an analyte sensor configured and arranged to determine the concentration of the analyte from 500 nL or less of body fluid"

('164 Patent, Claim 16)

5) "holding the sample in a non-flowing manner within the sample chamber of the analyte sensor"

('164 Patent, Claim 16)

ANALYSIS

1. Construction of "sample transfer path"

The parties dispute the meaning of the term "sample transfer path" which appears in claim 11 of the '890 patent. The claim reads as follows:

> 11. An electrode strip for use in an electrochemical sensor for measuring a compound in a sample, comprising an elongated electrode support defining a **sample transfer path** for directional flow of the sample from an application point along said electrode support...

Plaintiffs contend that the proper construction of the term is "the route along which a sample moves", whereas Defendant proposes that term means "an area of mesh layer not covered by screen printing ink in which the sample travels from the application point to the electrodes."

In support of their construction, Defendant cites the prosecution history. In a September 26, 1996 letter from the United States Patent and Trademark Office (PTO) entitled "Notice of Allowability", the patent examiner stated:

> The following is an Examiner's Statement of Reasons for Allowance: The prior art of record fails to teach the key to the applicant's instant invention which is (1) a plurality of mesh layers interposed in an enclosed space between the cover layer and electrodes and (2) a sample transfer path where the electrodes are in the sample path. Applicant shows that *the sample path is the area of the mesh layer that is not covered by the screen printing ink, as shown*...
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> (Mehta Decl., Exh. C) (emphasis added).

Defendant argues that this statement indicates a mutual understanding between Plaintiffs and the examiner that the term "sample transfer path" meant "the area of the mesh layer that is not covered by the screen printing ink" and that the grant of the amendment was contingent on such an understanding. Defendant further contends that Plaintiff's failure to object to the examiner's

statements amounts an adoption of these limitations. The Court does not agree. The meaning of Plaintiffs' failure to object is clearly ambiguous and does not constitute a "manifest exclusion or restriction" of the scope of the patent. *Phillips* at 1318.

Furthermore, it is not clear that the cited comments even apply to Claim 11. The '890 patent contains 21 claims in total. Several of the other claims of the '890 patent contain explicit "mesh layer" limitations, whereas Claim 11 does not. Although the examiner did not specify which claims were the subject of his comments, based upon his use of the term "mesh layer", it seems likely that the examiner was referring to one of the claims which explicitly included a "mesh layer" limitation. For example, Claim 1 asserts "...[a] covering layer having an aperture for receiving a sample into said enclosed space; and *a plurality of mesh layers* interposed in said enclosed space between said covering layer and said electrodes." ('890 Patent, Claim 1). Claim 3, which is dependent on Claim 1, adds "[t]he strip of claim 1 wherein said mesh layers define a path for directional flow of sample from said aperture through said enclosed space towards said working and reference electrodes, and said reference electrode is downstream from said working electrode in the direction of said flow." ('890 Patent, Claim 3). By contrast, Claim 11 does not even use the term "mesh." Moreover, Claim 13, which is dependent on Claim 11, explicitly adds the following limitation: " a plurality of superimposed mesh layers disposed along said sample transfer path." The fact that a dependent claim explicitly adds a "mesh layer" limitation implies that Claim 11 contains no such restriction. See *Tandon Corp. v. U.S. Intern. Trade Com'n,* 831 F.2d 1017, 1023 (Fed. Cir. 1987). The Court finds that Defendant has not demonstrated that Plaintiffs conceded a "mesh layer" limitation in Claim 11 during the prosecution of the patent; the Court declines to read in such a restriction now.[2]

The Court next turns to Plaintiffs' proposed reading. Plaintiffs' construction employs the ordinary and customary meaning of the term "path" and is supported by the context of the words

[2]Defendant also cites the preferred embodiment portion of the specification in support of their argument. Defendant points to language which states that "the periphery of the mesh...surrounds and defines a suitable sample transfer path" and that "the mesh layers preferably define a path for directional flow of the sample." Again, the Court is unpersuaded that these citations establish the presence of a mesh layer limitation in Claim 11. It is more likely that this language applies to the claims described above which include explicit mesh layer elements. Moreover, it is improper to read in a limitation from the preferred embodiment where, as here, there are no "words or expressions of manifest exclusion or restriction." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 905 (Fed. Cir. 2004).

following the contested phrase.[3] Immediately following the disputed term, Claim 11 states that the "sample transfer path" is for "directional flow of the sample from an application point along said electrode support." In other words, the path is the route upon which the sample travels as it moves from the application point to the electrodes. Accordingly, the Court construes "sample transfer path" as "route along which the sample moves."

2. Construction of "directional flow"

The parties next seek construction of the term "directional flow", which is found in Claim 11 of the '890 patent as follows:

> 11. An electrode strip...comprising: an elongated electrode support defining a sample transfer path for **directional flow** of the sample from an application point along said electrode support...

Plaintiffs urge the Court to interpret "directional flow" as "substantially linear movement of a fluid" and whereas Defendant proposes "flow of a sample in a uniform manner in the sample transfer path mesh layer." Defendant contends that the term "directional flow" necessarily implies the presence of a mesh layer since that is the only method disclosed in the specification for creating a directional flow. The Court is not persuaded by this argument. Defendant points to nothing in the intrinsic evidence indicating that the inventor intended that the structure guiding the sample through the electrode support to be limited to "mesh layers." The plain language of Claim 11 indicates no such limitation. For reasons similar to those articulated above, Defendant's interpretation is undermined by the fact that subsequent dependent claims explicitly *add* a mesh layer limitation. See, '890 Patent, Claims 13-21. This implies that Claim 11, from which the dependent claims are derived, contains no such limitation. *Id.* Defendant's proposed construction would effectively require the Court to read in an additional limitation from the specification, which the Court declines to do. See *Electro Medical Systems, S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994)("Claims are not to be interpreted by adding limitations appearing only in the specification.")

The specification does shed some light on the intended meaning of the term "directional

[3]The American Heritage Dictionary defines "path" as "the route or course along which something moves." (Plaintiff's Initial Markman Brief, Exh. 3, American Heritage Dictionary, 1991).

flow." The specification states, "[t]he preferred embodiments are those where the reference electrode... lies downstream (in the direction of sample flow) of the working electrode...and a remote application point at an aperture...for the sample is provided upstream of the reference electrode..." ('890 Patent, 4:44-48). The use of the terms "downstream" and "upstream" indicate that transfer path is intended to orient and guide the sample in a particular direction, as in the described embodiment, where the path is structured to have the sample flow from the aperture opening to the reference electrode. There is further support for this interpretation of "directional" flow as a guided orientation of the sample. The claim language immediately following the disputed term indicates that the intended orientation of the sample is "*from* an application point" "*along*" the electrode support, indicating that the claimed structure is designed to guide the sample along a specific path. Accordingly, the Court construes "directional flow", in light of the specification, as "the orientation and guidance in a particular direction."

3. Construction of "unassisted flow"

The next term to be construed appears in Claim 16 of the '164 patent as follows:

> A method for determining a concentration of an analyte in a body fluid of a patient, comprising the steps of: creating ***an unassisted flow*** of a body fluid from the patient; transporting a portion of the body fluid into an analyte sensor configured and arranged to determine the concentration of the analyte from 500 nL or less of body fluid...

Plaintiffs propose a construction of "unassisted flow" as "creating a flow of a body fluid from a person without the aid of a mechanical or electro-mechanical device such as a syringe which draws the fluid from the body" and Defendant as "the emission of a useful sample volume obtained by lancing a portion of the skin without milking (i.e. without squeezing, massage) or using a syringe."

The Court finds little support for Plaintiffs' proposed construction. Plaintiffs' interpretation limits the scope of the term "unassisted" so as to only exclude flow assistance provided by mechanical and electro-mechanical devices. This interpretation would effectively bring within the

ambit of the claim "flow promotion" through non-mechanical means such as "milking"[4] in which blood flow is induced through the application of hand pressure. The specification belies Plaintiffs' contention that the term "unassisted" was only intended to exclude processes using machines or devices. The patent states:

> Currently available technology measures bioanalytes in relatively large sample volumes, e.g., generally requiring 3 microliters or more of blood or other biological fluid. These fluid samples are obtained from a patient, for example, using a needle and syringe, or by lancing a portion of the skin such as the fingertip and "milking" the area to obtain a useful sample volume....Less painful methods for obtaining a sample are known such as lancing the arm or thigh, which have a lower nerve ending density. However, lancing the body in the preferred regions typically produces submicroliter samples of blood...It would therefore be desirable...to develop [an] easy to use blood analyte sensor, capable of performing an accurate and sensitive analysis of the concentration of analytes in a small volume of sample.
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> '164 patent, 1:15-36.

This paragraph suggests that one of the major improvements of the '164 patent over the prior art was that it permitted users to measure much smaller volumes of biological fluids than had previously been possible. According to the specification, prior to the '164 patent, users had to employ mechanical devices or physical processes such as hand "milking"[5] in order to draw out samples large enough to be measured by the then existing techniques. It stands to reason that if the inventors sought to eliminate the need to induce additional flow of fluid to create samples large enough to be measured, the improvements would have been applicable to any means of promoting additional flow, whether mechanical or through "milking." The specification makes it clear that the inventors intended to measure the small amounts of biological fluid[6] capable of being generated

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[4]In this context, "milking" refers to the coaxing of blood flow by squeezing, or applying hand pressure to a flow area.

[5]The Court also rejects Defendant's construction that unassisted flow necessarily requires "lancing." The ordinary meaning of "unassisted flow" does not suggest that it be limited to instances where the measured bodily fluid has been produced due to lancing.

[6]The specification defines "biological fluid" as "any body fluid in which the analyte can e measured, for example, blood, interstitial fluid, dermal fluid, sweat, and tears." '164 Patent, 4:50-52.

without "additional assistance."[7] Plaintiffs cite no evidence indicating that the term "unassisted" was intended to exclude only mechanical devices such as syringes. The inventors deliberately included the term "unassisted" in their claim; the Court must attempt to give meaning to every word in a claim when construing terms. *Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*, 93 F.3d 1572, 1579 (Fed.Cir.1996). Presumably, the inventors could have modified the term to encompass only mechanical assistance had they so intended. In light of the specification and the ordinary meaning of the terms, the Court construes, "unassisted flow" to mean "flow without the aid of any additional process or device to draw out more fluid than that which occurs once the flow has been initiated."

4. Construction of "an analyte sensor configured and arranged to determine the concentration of the analyte from 500 nL or less of body fluid"

The parties next seek to construe the phrase "an analyte sensor configured and arranged to determine the concentration of the analyte from 500 nL or less of body fluid" found in Claim 16 of the '164 patent as follows:

> A method for determining a concentration of an analyte in a body fluid of a patient, comprising the steps of: creating an unassisted flow of a body fluid from the patient; transporting a portion of the body fluid into **an analyte sensor configured and arranged to determine the concentration of the analyte from 500 nL or less of body fluid.**..

Plaintiffs argue for the construction "a device to detect the presence and/or measure the concentration of an analyte that is constructed and disposed to determine the concentration of the analyte from 500 nL or less of body fluid" and Defendant for the construction "a coulometric sensor where the electrodes are separated by no more than .2 mm and the mediator is immobilized (i.e. entrapped or chemically bound) to the surface of the working electrode."

Defendant first contends that Claim 16 expresses a means plus function claim, and as such, is limited to the structures and materials disclosed in the specification for performing the invention

[7]For example, unassisted flow would include the situation where a fingertip is punctured with a lance, and blood naturally flows to the surface of the finger at the puncture point

pursuant to 35 U.S.C. § 112 ¶ 6. It is not necessary to include the word "means" in the language of a means-plus-function claim. *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1358 (Fed.Cir.2004). However, a claim which does not include the word "means" raises a rebuttable presumption that the claim does not recite a means plus function element. *Id.* Defendant contends that the language at issue states a means-plus-function element because the claim does not convey a well-defined structure for an analyte sensor that is "configured and arranged to determine the concentration of the analyte from 500 nL or less of body fluid." The Court finds this argument unavailing. The contested language recites a step in Plaintiffs' method claim, and the terminology "configured and arranged" states a limitation requiring the presence of an analyte sensor which has been designed for the purpose of determining the concentration of analytes in volumes less than 500 nL. Defendant points to nothing in the record indicating that Plaintiffs intended this language to recite a means-plus-function element within their process claim. Accordingly, the Court finds that Defendant has failed to overcome the presumption created by the absence of the "means for" language.

Defendant next contends that the invention is limited to only those analyte sensors which use the process of coulometry[8] to determine the concentration of analytes.[9] Defendant argue that the specification frames the invention within the context of the coulometric technique and that Plaintiffs specifically disclaimed other analytical methods during the patent application process. Defendant cites a portion of the prosecution history in which Plaintiffs distinguished the invention from the prior art before the PTO examiner, stating:

> Claim 133-142 were rejected...as being unpatentable over [prior art] Niwa....The claim 133, and claims 134-147 by dependency on claim 133, are directed to a method for determining the concentration of an analyte in a sample by coulometry....Niwa is cited as teaching the determination of the concentration of an analyte by amperometric methods...The examiner notes that this reference fails to teach the determination of an analyte by coulometery....The advantages provided by a coulometric measurement as compared with other electrochemical methods are described in the specification....these advantages include temperature independence...and a much smaller sample size.

[8]Coulometry is a method for indirectly determining the concentration of a substance in a solution by submitting the substance to an electrolysis reaction, and then measuring the amount of electricity released during the reaction.

[9]As its name suggests "analyte" is the generic term for any substance which is to be analyzed.

> Mehta Declaration, Exh. 5, Plaintiffs Amendment Application to USPTO, Dec. 16, 1998, 4-6.

Defendant asserts that these concessions were directed toward Claim 16, and that Plaintiffs limited the scope of Claim 16 in making these statements. However, there is no indication that this discussion was directed toward Claim 16, which is the claim at issue here. Rather, it appears that the portion of the prosecution history cited by Defendant was actually directed toward *other* claims which specifically include a coulometry limitation in the claim language.[10] For example, Claim 1 recites, "[a] method for determining a concentration of an analyte in body fluid, comprising the steps of: collecting a sample of body fluid of about 500 nL....and determining the concentration of the analyte in the sample using a *coulometric* technique. " ('164 Patent, Claim 1)(emphasis added). Plaintiffs explicitly limit the method in Claim 1 to the use of the coulometric process. By contrast, the method recited in Claim 16 does not identify any specific process for determining the concentration of an analyte.

Defendant's argument is undermined by the fact that Plaintiffs do identify specific techniques for determining analyte concentration in Claims 33, 34, and 35, which are dependent upon Claim 16. Plaintiffs limit the methods claimed there to coulometry, amperometry, and optics, respectively.[11], Under the doctrine of claim differentiation, "[t]here is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims." *Tandon Corp. v. U.S. Intern. Trade Com'n*, 831 F.2d 1017, 1023 (Fed. Cir. 1987). "To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant." *Id.* Applying the doctrine of claim differentiation, the fact that Plaintiffs identify specific processes in

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[10]It appears that Claim 16 was originally application Claim number148, and that the portion of the prosecution history cited by Defendant does not refer to Claim 16 at all, but instead, to claims 133-147, which became Claims 1-15 in the issued patent. See Plaintiff's Revised Initial Markman Brief, Exh. 10 at TH0035873 (mapping the application claim numbers to the patent claim numbers.)

[11]The '164 patent states Claims 33 and 34 as follows, "33. The method of claim 26, wherein determining the concentration of the analyte comprises determining the concentration of the analyte using a coulometric technique. 34. The method of claim 26, wherein determining the concentration of the analyte comprises determining the concentration of the analyte using an amperometry." Claim 26 in turn is dependent on claim 16, as follows, "26. The method of claim 16, wherein the analyte sensor is an electrochemical sensor."

Claims 33, 34, and 35, which are all dependent on Claim 16, implies that no such limitation exists in Claim 16.[12] Therefore, Defendant's contention that Claim 16 includes a coulometry limitation is belied by the limitations expressed in dependent Claims 34 and 35, which specifically identify alternative processes to coulometry.[13]

Defendant also argues that Claim 16 should be limited to sensors with electrodes located within 0.2 mm of each other and containing immobilized mediators. In support of this argument, Defendant cites the preferred embodiment portion of the specification in which Plaintiffs state, "[t]ypically, the thickness of the sample chamber [should be] less than about 0.2 mm." ('164 Patent, 10:50-54). The preferred embodiment section also states, "More preferably, the redox mediators of the present invention are bound or otherwise immobilized on the working electrode to prevent undesirable leaching of the mediator into the sample. A diffusing or leachable (i.e., releasable) redox mediator is not desirable when the working and counter electrodes are close together (i.e., when the electrodes are separated by less than about 1 mm), because a large background signal is typically produced as the unbound mediator shuttles electrons between the working and counter electrodes, rather than between the analyte and the working electrode. This and other problems have hindered the development of low resistance cells and increased the minimum sample size required for determination of analyte concentration." ('164 Patent, 6:26-40). The Court finds this argument unpersuasive. It is improper to read a limitation from the preferred embodiment into the claims. *Liebel-Flarsheim* at 905. Defendant's proposed reading would improperly impose limitations from the preferred embodiment. In light of the above analysis and the plain and ordinary meaning of the

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[12]Plaintiffs assert, and the Court agrees, that reading Defendant's coulometry limitation into Claim 16 would impermissibly render redundant or irreconcilable at least five other dependent claim terms, viz. claims 26, 27, 33, 34, 35.

[13]Defendant also contends that the specification "disparages" non-coulometric methods such as amperometry and that Plaintiffs disavowal amounts to a disclaimer of such methods. For this proposition, Defendant cites *Honeywell Intern., Inc. v. ITT Industries, Inc.*, 452 F.3d 1312 (Fed. Cir. 2006). The *Honeywell* court stated that where "the written description has gone beyond expressing the patentee's preference for one material over another....repeated derogatory statements concerning one type of material are the equivalent of disavowal of that subject matter from the scope of the patent's claims." *Id.* at 1318. Defendant argues that Plaintiffs' repeated affirmations, within the specification, of the superiority of the coulometric technique amounts to a disavowal of non-coulometric techniques. The Court finds this argument unavailing. Defendant misconstrues the scope of Plaintiffs' statements. While the specification clearly states a *preference* for the coulometric technique, it does not *disavow* non-coulometric techniques. To the contrary, the patent specifically claims several non-coulometric techniques. (See Claims 34 and 35). It would make little sene to find that Plaintiffs disclaimed a technique that they claim in the same patent. Accordingly, the Court finds *Honeywell* distinguishable on this basis.

terms, the Court construes the disputed phrase to mean, "a device designed to measure the concentration of an analyte given a sample of 500 nL or less of body fluid."

5. Construction of "holding the sample in a non-flowing manner within the sample chamber"

The parties next dispute the construction of the phrase "holding the sample in a non-flowing manner within the sample chamber", found in Claim 16. Plaintiffs assert that the term means "the sample remains within the sample chamber during measurement rather than flowing through the sensor during measurement as it would in a flow cell" and Defendant contends that it means "the sample is at rest in the sample chamber during the test." Defendant notes that the patent examiner required the inclusion of the term "non-flowing" before the PTO would allow the patent, and that the inclusion of this term was significant. The plain and ordinary meaning of "non-flowing manner" indicates that the sample must be stopped, rather than moving. In the preferred embodiment portion of the specification, the patent states, "The sensor can also be used in conjunction with a flowing sample stream. In this configuration, the sample stream is made to flow through a sample chamber. The flow is stopped periodically and the concentration of the analyte is determined by electrochemical method, such as coulometry. After the measurement, the flow is resumed, thereby removing the sample from the sensor." ('164 Patent, 11:40-43).[14] In another section, the patent states, "As the fluid stream flowed through the sensor, a steady-state current proportional to the lactate concentration was measured. At periodic intervals the fluid flow was stopped and current was allowed to flow between the electrodes..." ('164 Patent, 23:9-14). As the specification indicates, it is important to the proper functioning of the sensor that the sample be at least temporarily immobilized during measurement. Accordingly, the Court construes the term to mean "the sample is not moving

[14]The preferred embodiment continues, "[a]lternatively, sample may flow through the chamber at a very slow rate, such that all of the analyte is electrolyzed in transit, yielding a current dependent only upon analyte concentration and flow rate." ('164 Patent, 11:44-46). However, since this description of the sample as flowing at a very slow rate is directly at odds with the plain and ordinary meaning of "non-flowing", the Court finds that this language does not describe those claims which contain a "non-flowing" limitation, such as Claim 16.

in the sample chamber during the measurement."

CONCLUSION

For the foregoing reasons, the Court construes the disputed terms as follows:

1) "sample transfer path" as **"route along which the sample moves"**

2) "directional flow" as **"the orientation and guidance in a particular direction"**

3) "unassisted flow" as **"flow without the aid of any additional process or device to draw out more fluid than that which occurs once the flow has been initiated."**

4) "an analyte sensor configured and arranged to determine the concentration of the analyte from 500 nL or less of body fluid" as **"a device designed to measure the concentration of an analyte given a sample of 500 nL or less of body fluid**"

5) "holding the sample in a non-flowing manner within the sample chamber of the analyte sensor" as **"the sample is not moving in the sample chamber during the measurement"**

IT IS SO ORDERED.

Dated: August 31, 2006

MARTIN J. JENKINS
UNITED STATES DISTRICT JUDGE